BUSINESSEUROPE

THE DIRECTOR GENERAL

Baroness Ashton
Member of the European Commission
200 rue de la Loi
1049 Bruxelles

12 January 2009

Dear Commissioner,

Reflecting the interests of Europe's highly innovative industries, BUSINESSEUROPE has profound continuing concerns about the EU position on amendment of TRIPS to create a binding international obligation to disclose source and/or origin of genetic resources (GR), with or without traditional knowledge (TK).

European business remains fully committed in the ongoing negotiations on the Convention on Biological Diversity regarding a holistic Access and Benefit Sharing International Regime.

However, BUSINESSEUROPE would like to reiterate its opposition to a reopening of the TRIPs Agreement to provide for mandatory disclosure of source or origin of genetic resources within the Doha Round.

You will find at annex detailed information compiled in response to a request from former Commissioner Mandelson,on the negative role that mandatory patent disclosure policies have played in Brazil and India, as an integral part of their domestic access and benefit-sharing (ABS) regimes.

Far from creating development benefits and greater certainty for industry, mandatory disclosure provisions adopted by developing countries have frozen sustainable commercialisation of biodiverse resources wherever they have been adopted, harming innovators and local communities, not just in Brazil and India, but also in Colombia, Peru, the Philippines, South Africa, and elsewhere. In all of these countries, mandatory disclosure measures have increased uncertainty for industry, and have slowed or halted bio-prospecting.

Additionally, even if the EU were to seek a WTO TRIPS amendment excluding patent revocation or cancellation as a penalty, this would be another highly contentious issue, where the EU could not be confident of the outcome. The leading advocates on this issue have never conceded this point. In fact, existing regimes go much further, include both open-ended nature of grounds for patent challenge and even cancellation or revocation of patents after grant, clear incentives for competing firms to instigate litigation or for engagement of NGOs opposing grant of any patents for genetic resources/traditional knowledge inventions.

Even if enforcement of a mandatory patent disclosure regime were to be taken outside the patent system, companies have seen the great difficulty in simply gaining initial patent approval in such regimes. Far from being a simple solution, Brazil, Peru and India, for example, have established separate bureaucracies to approve possible genetic resources-related patent applications.

In addition, the wide latitude of non-governmental organisations and pressure groups to challenge every aspect of the bio-prospecting process (from prior informed consent to mutually agreed terms), raises concerns about its impact on the innovation capacity of European life-science companies.

Understanding the complexity of WTO negotiations and the importance of success in the Doha Round in the current economic and financial environment, we would appreciate an opportunity to meet you and discuss these key issues further, exploring more positive alternatives, to address the serious concerns of European business.

Yours sincerely,

Best regards,

Philippe de Buck

BUSINESSEUROPE

ANNEX TO THE LETTER TO COMMISSIONER ASHTON

- In Brazil, policy-makers and scholars concede that the current Access and Benefit sharing (ABS) regime, including both mandatory patent disclosure and discrimination against genetic resource patents, has made it extremely difficult for innovative life science companies to invest in that country. More broadly, Brazil's domestic ABS regime has shut down international cooperation and investment in commercial and non-commercial research relating to Brazil's biodiverse resources. In recognition of the failure of its overall ABS policies, in 2008 Brazil initiated a period of national and international review of new proposed policies to reform Brazil's national regime, including policies affecting patent disclosure. Unfortunately, these proposed amendments, while including some improvements, would also introduce additional roadblocks for sustainable commercialisation of genetic resource inventions. In the meantime, the legislative process has stalled with no progress expected in the near term in improving Brazil's dysfunctional mandatory disclosure regime. In this context, patent disclosure is symptomatic of the negative approach that Brazil has taken to ABS, an approach that has not succeeded overall in generating benefits.

- In India, stakeholders, including government officials, NGOs, think-tanks and industry, readily acknowledge that India's ABS national regime has fallen short of expectations and has failed to generate meaningful benefits from sustainable use of India's mega-diverse genetic resources and traditional knowledge. The National Biodiversity Authority (NBA), which is responsible for giving formal approval to applicants both prior to bio-prospecting applications and prior to filing for patent protection, has proven incapable of taking timely decisions and discriminates against foreign companies. Like Brazil, India's ABS national regime is viewed as a bureaucratic labyrinth that (unintentionally) discourages investment in India's mega-diverse states. For example, highly regarded AYUSH (Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy) therapies and products have not found their way from India's mega-diverse states into the global market place. Consequently, Indian traditional medicines and related active ingredients enjoy less than 2% of an estimated $ 60 billion global market. India's ABS regime, including stringent mandatory patent disclosure obligations, creates enormous bottlenecks, resulting in uncertainty for industry and precluding domestic and foreign investment.